US Environmental Protection Agency
Office of Pesticide Programs

Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for Master Schedule Preparation

SOP Number: QA-04-03

Date Revised: 04-11-07

Superseded SOP: QA-04-02 Master Schedule Preparation

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure for Master Schedule Preparation

SOP Number: QA-04-03

Date Revised: 04-11-07

Initiated By: _____ Date: ___/___/___

Print Name:_____

QA Review: _____ Date: ___/___/___

Print Name:_____
QA Officer

Approved By: _____ Date: ___/___/___

Print Name:_____
Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

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1.0 SCOPE AND APPLICATION:

1.1 As a requirement of the EPA Good Laboratory Practice Standards (GLPs) (see ref. 15.1) the Quality Assurance Unit (QAU) shall maintain a Master Schedule of all studies. The Master Schedule shall be indexed and contain the following information: study protocol number or project code, test substance, test system or description of study, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director. This protocol describes the method for preparing, updating, and using the laboratory's Master Schedule.

2.0 DEFINITIONS:

2.1 GLP = Good Laboratory Practice Standards (EPA GLPs are codified in 40 CFR Part 160)

2.2 Test substance = A substance or mixture administered or added to a test system in a study (see ref. 15.1), for example, EPA-registered hard surface hospital disinfectants/tuberculocides, including the products' active and inert ingredients

2.3 Test system = Any animal, plant, microorganism, or chemical or physical matrix to which the test or control substance is administered or added for study (see ref. 15.1), typically the test microorganism for method under investigation [e.g., *Staphylococcus aureus*, *Pseudomonas aeruginosa*, or *Mycobacterium bovis* (BCG)] used in efficacy testing of EPA-registered hard surface hospital disinfectants/ tuberculocides]

2.4 Study Sponsor = Individual or entity who initiates and supports a study [e.g., OPP Microbiology Laboratory, Antimicrobials Division (AD), Biopesticides and Pollution Prevention Division (BPPD)]

2.5 Study Director = Individual responsible for the overall conduct of the study (typically the laboratory's Team Leader, assigned individual or Principal Investigator)

2.6 Nature of study = Test method used in the study (e.g., test method used to determine the efficacy of an EPA-registered hard surface hospital disinfectant/tuberculocide, such as the AOAC Germicidal Spray Products Test)

2.7 Study Initiation Date = The date the study is initiated

2.8 Study Completion Date = The date that the data collection activities are

completed

2.9 Study Status = Current status of the study (e.g., Study in progress, Report in progress, Complete, or Not conclusive/repeat test)

2.10 QAU = Quality Assurance Unit; includes the Quality Assurance Officers (QAO)

2.11 Laboratory = OPP Microbiology Laboratory located in the Environmental Science Center, Ft. Meade, Maryland

2.12 Team Leader = Individual who oversees and technically directs the laboratory's analysts

2.13 Study Protocol Number = For product performance tests conducted according to GLPs as part of the Agency's Antimicrobial Testing Program, a unique study protocol number is assigned to each study protocol. Study protocol numbers are assigned in numerical order for each calendar year (e.g., The number assigned to the first study protocol of 2007 would be 2007-01; the number assigned to the second study protocol of 2007 would be 2007-02, etc.). The text of the study protocol identifies the title, purpose, test identification, test substance, controls, sponsor, test facility, proposed experimental start date, proposed experimental completion date, test system, and experimental design of the study

2.14 QAPP = Quality Assurance Project Plan

2.15 Project Code = Project codes are used to assign a unique identifier to studies that are not product performance tests under the Antimicrobial Testing Program

2.16 All product performance test studies will be tracked in the Master Schedule by the study protocol number, a unique identifier. Studies associated with a laboratory QAPP will be assigned a unique code using the following format: QAPP number-project code, study number

2.16.1 Example: "QAPP2003-01- Evaluation of Spore Recovery on Trypticase Soy Agar" would be represented by "QAPP2003-01-SR-01" where "QAPP2003-01" is the QAPP number, "SR" is the project code and "-01" is the study number

2.16.2 Studies which are not associated with a QAPP will be assigned a unique code using the following format: Code for study name-study number, for example: A study that is entitled "Glass Slide Carrier Study" and is the first one under that topic would be coded:

"GSCS-01" where "GSCS" represents the study title and "-01" indicates that this is the first experiment under that title

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

10.1 Master Schedule organization (see 16.1): According to GLPs (see ref. 15.1) the Master Schedule must be indexed by test substance. The test substance for each study is identified and described in the study protocol, statements of work, research proposals, or OPP Microbiology Laboratory study notebook. Because study protocol numbers and project codes are unique identifiers for each study conducted in the laboratory, it is practical to index the Master Schedule by the study protocol number/project code. Therefore, indexing by study protocol number/project code refers the reader to study documentation describing the test substance.

10.2 Master Schedule Preparation (see 16.1): The Master Schedule will be maintained primarily by the QAU as an electronic document. The Branch Chief, Study Director, Team Leader, or lead analyst will update the Master Schedule as needed (e. g. add information concerning study protocol #, test substance, study sponsor and nature of study). The Master Schedule will contain information pertaining to all unique data collection activities conducted in the laboratory during the current calendar year. A new Master Schedule will be created for each calendar year.

10.2.1 **Study Protocol Number/Project Code.** In this column, enter the

study protocol number or project code assigned to the study (see sections 2.13 and 2.15).

10.2.2 **Test Substance (EPA Reg. No. /Product).** Enter the test substance (see section 2.2), including EPA Registration Number, if applicable, and product name (e.g., EPA-registered hospital disinfectant/tuberculocide to be subjected to efficacy testing).

10.2.3 **Study Sponsor/Study Director.** Enter the Study Sponsor(s) (see section 2.4) and Study Director (see section 2.5).

10.2.4 **Nature of Study.** Enter the test system (see section 2.3) and nature of the study (e.g., test method) (see section 2.6), or a brief description of the study.

10.2.5 **Study Initiation Date.** Enter the date that the data collection activities in the laboratory are initiated.

10.2.6 **Study Completion Date.** Enter the date that the data collection activities in the laboratory are completed.

10.2.7 **QAU Inspection.** Enter the elements of the testing/reporting process that have been or will be audited by the QAO or the alternate QAO during the duration of the study. Examples of such elements may include, but are not limited to, laboratory notebooks, the Study Protocol, certain procedures of the study itself, the draft report, and the final report.

10.2.8 **QAU Inspector.** Enter the first initial and the last name of the QAO conducting the audit of each of the pertinent elements described in section 10.2.7.

10.2.9 **Final Report Approval Date (QAU).** Enter the date, using the six-digit MM-DD-YY format, that the QAO signed the Quality Assurance Review Form (see SOP ADM-01, Preparation of Performance Reports). Enter “Not applicable” if the study was invalidated and must be repeated.

10.2.10 **Study Status.** Enter the most applicable of the following: Study in progress, Report in progress, Complete, or Not conclusive/repeat test.

10.2.10.1 Enter “Study in progress” to designate the time period beginning with the study initiation date and ending with the study completion or study termination date.

10.2.10.2 Enter “Report in progress” to designate the time period during which the report or data summary is being compiled and reviewed (see SOP ADM-01, Preparation of Performance Reports).

10.2.10.3 Enter “Complete” as directed below:

10.2.10.3.1 For studies requiring the development of a report (e.g., efficacy testing for the Antimicrobial Testing Program), enter “Complete” once the final report has been reviewed and approved by the QAO and Branch Chief.

10.2.10.3.2 For all other studies, enter “Complete” once the Team Leader and/or Branch Chief have reviewed the summary of the data.

10.2.10.4 Enter “Not conclusive/repeat test” to indicate that the study was invalidated (e.g., due to an event such as low carrier counts, etc.) and/or that the study must be repeated. Data from a study that must be repeated will be compiled and submitted to the Team Leader and QAO for review. Preparation of a final report (see SOP ADM-01, Preparation of Performance Reports) or data summary is at the discretion of the Study Director or Branch Chief.

10.3 Updating the Master Schedule:

10.3.1 The QAU, Branch Chief, Study Director, Team Leader, or lead analyst may update the Master Schedule as needed to ensure that the schedule provides an accurate and concise assessment, and current status of each study. The QAU will ensure on a regular basis that the data in the Master Schedule is current and up-to-date.

10.4 Using the Master Schedule:

10.4.1 The QAU shall comply with GLPs (see ref. 15.1), and maintain a hard copy of the Master Schedule of studies (see section 12.1). In

addition, the Master Schedule will be used to develop test method auditing schedules (see SOP QA-01, Operations of the Quality Assurance Unit).

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Information pertinent to each study will be entered electronically into the Master Schedule (see 16.1) (g:\user\share\appb\Antimicrobial Testing Program\Master Schedule\Current Master Schedule). The QAU will backup the electronic Master Schedule file on a quarterly basis. At the end of each quarter, the QAU will print out the Master Schedule for the current calendar year, sign and date it, and archive it in the Master Schedule Record Book. The Master Schedule Record Book will be kept in a secured file cabinet in file room D217. Archived records are subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practice Standards. Appropriate quality control measures are integrated into each SOP.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Data entry errors discovered in the Master Schedule will be immediately corrected in the electronic version. If an error is identified in a retired Master Schedule file (i.e., from a previous year) or a section of the current year's Master Schedule that has already been printed (section 12.1), the QAU will print out the page from the electronic Master Schedule file that contains the data entry error, entry error the incorrect information, and write in the corrected information. The QAU will then make the correction in the electronic Master Schedule file and print out the corrected page. The printed page containing the data entry error and the printed page containing the corrected information will be stapled together and placed in the Master Schedule Record Book.

15.0 REFERENCES:

15.1 US EPA Good Laboratory Practices, Title 40 Code of Federal Regulations (CFR) Part 160.

16.0 FORMS AND DATA SHEETS:

16.1 Master Schedule

Master Schedule
OPP Microbiology Laboratory

Calender Year:_____ Quarter:_____

Study Protocol Number/ Project Code	Test Substance (EPA Reg. No./Product)	Study Sponsor/ Study Director/ Test Coordinator	Test System/Method or Description of Study	Study Initiation Date	QAU Inspection/ QAU Inspector	Study Status	Study Completion Date	Final Report Approval Date (QAU)